4WD-RCRA

MEMORANDUM

SUBJECT: Risk Assessments Within the HSWA Program

FROM: Corrective Action Standing Team
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THROUGH: Alan Farmer, Chief /s/ August 24, 1996
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TO: RCRA Staff

Issue

During implementation of the corrective action program covered by the 1984 Hazardous and Solid Waste Amendments (HSWA) to the Resource Conservation and Recovery Act (RCRA), the U.S. Environmental Protection Agency (EPA) - Region 4 has encountered numerous facilities which desire to use risk assessments to aid/direct the remedial action decision making process. Until recently, individual HSWA Facility Coordinators have been dealing with this issue with incomplete regional guidance on:

1) What kind of risk assessment is acceptable (i.e., is a CERCLA risk assessment acceptable for RCRA)?

2) When or where within the HSWA Corrective Action Program are risk assessments appropriate?

3) Are risk assessments needed at every facility?

This memo briefly addresses these three (3) questions. The memo also serves to transmit several supplemental Human Health Assessment Risk Bulletins generated by Region 4's Office of

Technical Services (Attachment 1). These Region 4 Risk Bulletins give a brief explanation of each stage of a CERCLA baseline risk assessment. HSWA Facility Coordinators should review these bulletins to expand their understanding of what is expected from a full site-specific human health risk assessment produced under

the HSWA Program.[1] Supplemental Region 4 Risk Bulletins which relate to ecological risk assessments are also available through Region 4's Office of Technical Services (OTS). Unless otherwise stated, use of the term "risk assessment" in this memo relates solely to human health risk assessments.

I. Human Health Risk Assessments in CERCLA

Historically, most EPA risk assessment guidance for environmental restoration projects has been developed for the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). Consequently, most of the risk assessment work for remedial projects has been confined to the CERCLA Program.

As outlined in the attached Region 4 Risk Bulletins, a full site-specific risk assessment (i.e., a CERCLA Baseline Risk Assessment) includes the following phases: Data Collection and Evaluation, Toxicity Assessment, Exposures Assessment and Risk Characterization. By comparing environmental media data to relevant screening levels, a list of Chemicals of Potential Concern (COPC) is generated.[2] A full site-specific risk

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[1] A full site-specific risk assessment in the HSWA Program is analogous to the baseline risk assessment in CERCLA. The primary goal of the baseline risk assessment is to provide risk managers with an understanding of actual and potential risks to human health and the environment from releases. The baseline risk assessment also clearly identifies any uncertainties associated with the assessment (see April 22, 1991, OSWER Directive 9355.0-03; Role of Baseline Risk Assessment in Superfund Remedy Selection Decisions).

[2] Note that in Region 4, standardized screening levels for non-carcinogenic constituents need to be adjusted to a level equivalent to a Hazard Quotient (HQ) of 0.1 before being used to select COPCs for a site-specific risk assessment (see Region 4 Bulletin Number 1). In practice, this adjustment means that any screening level generated with an HQ of 1 should be divided by 10 before use as a screening level in a site-specific risk assessment. This adjustment is made due to the possible additive toxicity of multiple chemicals at a facility. Note that an HQ of

assessment utilizes the COPC list and current and future exposure scenarios to evaluate facility risk. Once the site-specific risk assessment is complete, a list is generated of Chemicals of Concern (COC) that significantly contribute to a scenario (e.g., hypothetical future child, current youth trespasser, current adult construction worker, etc.; see Region 4 Risk Bulletin 5).

Chemicals of Concern in the CERCLA Program are defined as those constituents that significantly contribute to a pathway in an exposure scenario for a receptor that either exceeds a $10^{-4}$ cumulative site cancer risk or exceeds a non-carcinogenic hazard index (HI) of 1.[3] Note that these risk levels are frequently used as remediation triggers for CERCLA.[4] The exact level to be used as the remediation trigger is at the discretion of the risk manager but must be within the protective range. Once the risk is deemed unacceptable at a facility, Region 4 CERCLA risk assessments will include a section which stipulates Remedial Goal Options (RGOs). The RGOs present a range of human health risks (e.g., $10^{-4}$ through $10^{-6}$ risk level; HQ levels of 0.1, 1 and 3)

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1 is used in the following standardized lists: 1. Action levels and the methodology for calculating action levels presented in the 1990 Proposed Subpart S, 2. Generic soil screening levels and the associated methodology for calculating soil screening levels presented in the Soil Screening Guidance, 3. Risk numbers presented in the Region 3 Risk-Based Concentration Tables.

[3] The Hazard Index measures the overall risk posed by a mixture of hazardous constituents. The risk posed by an individual hazardous constituent is represented by its Hazard Quotient.

[4] Note that the term "remediation trigger" does not mean that a facility which exceeds the established remediation trigger is required to undergo <u>active</u> remediation. Instead, exceeding the remediation trigger designates that an evaluation of remedial alternatives is necessary. Some of these alternatives may take the form of passive remediation (e.g., natural attenuation) or remediation through a conditional remedy.

for all applicable environmental media. As necessary, the RGOs will include goals based on environmental concerns or State specific requirements (see Region 4 Risk Bulletin 5). The RGOs provide the basis for developing remediation plans to be examined during evaluation of remedial alternatives.

## II. Use of CERCLA Risk Assessments in the HSWA Corrective Action Program

Although the HSWA Program does not have a strong history of using risk assessments to provide facility coordinators with estimates of potential risks posed by contamination at a facility, clearly the same general procedures for performing a full site-specific risk assessment for CERCLA can be applied to the HSWA Program. In fact, risk assessments for any corrective action program should follow these same standard procedures.

The methodology, equations, standard intake assumptions, land use assumptions/guidance, etc. historically attributed to CERCLA risk assessments are appropriate for risk assessments performed for the HSWA Corrective Action Program. However, because the attached Region 4 Risk Bulletins were developed for use in the CERCLA Program, which must follow the National Contingency Plan (NCP), there may be some unforeseen deviations necessary to satisfy specific HSWA requirements or CERCLA risk assessment protocols which may not be necessary in the HSWA Program.

Although this memo encourages the use of CERCLA methodologies and assumptions for risk assessments performed for the HSWA Program, it should be understood that the science of risk assessment is in flux and technical criteria of today (e.g., opinions on determining appropriate land use, content of standardized equations, use of default exposure assumptions, etc.) may change in the future; therefore, risk assessments must be viewed as flexible tools which are open to improvements and new EPA interpretations. Regional risk assessors will keep abreast of these changes and inform HSWA Facility Coordinators as necessary.

## III. Relationship between the HSWA Corrective Action Process and the CERCLA Remedial Process

The main objective of the RCRA Facility Investigation (RFI) is to determine the nature and extent of releases from Solid Waste Management Unit (SWMUs) and Areas of Concern (AOCs). The comparable CERCLA stage for the RFI is the Remedial Investigation (RI). Once the RFI has characterized the distribution and concentration of all constituents by media, a comparison of the constituent's concentration to respective action levels is made.

Action levels are health- or environmental-based concentrations determined to be indicators for protection of human health or the environment. Action levels are generally derived using chemical-specific toxicity information and standardized exposure assumptions. Standardized action levels are often established at the more protective end of the risk range (e.g., $10^{-6}$ risk level) using conservative exposure and land use assumptions.[5] Note that the HSWA Program designates concentrations at an acceptable risk level as "action levels" while the equivalent CERCLA term for such acceptable concentrations is "screening level."

In the HSWA Program, the action level concept is used as a trigger for conducting additional corrective action activities (e.g., additional investigation and/or evaluation of remedial alternatives; see the 1990 Proposed Subpart S Rule (FR 55, July 27, 1990) and the 1996 Advanced Notice of Proposed Rulemaking (ANPRM; FR 61, May 1, 1996) for corrective action of releases from SWMUs). It is general practice for a Corrective Measures Study (CMS) to be submitted at any HSWA facility where standardized action levels have been exceeded. However, a determination that an evaluation of remedial alternatives is not necessary for a HSWA facility may be made if it can be shown that identified hazardous constituents pose no unacceptable risk to human health or the environment. This no further action demonstration is typically accomplished through either the

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[5] Since the Proposed Subpart S Rule was issued in 1990, toxicity data for many chemicals have changed. In addition, the Subpart S equations/assumptions are not the same equations/assumptions currently utilized by CERCLA; hence, HSWA Facility Coordinators should utilize updated action levels. Region 3 generates a quarterly Risk-Based Concentration Table which is an excellent source of current action or screening levels.

formulation of site-specific action levels[6] or through a full site-specific risk assessment.[7] In the CERCLA Program, a Feasibility Study (FS), the CERCLA equivalent to the CMS, is generally required when the risk associated with COPC exceeds established remediation triggers. CERCLA remediation triggers are customarily fixed at a $10^{-4}$ cumulative site risk level and a HI of 1 (see April 22, 1991, OSWER Directive 9355.0-03; Role of Baseline Risk Assessment in Superfund Remedy Selection Decisions).

Region 4 is unaware of any clear national position on the merits or disadvantages to the HSWA Program's use of the standard CERCLA remediation triggers. If a full site-specific risk assessment is utilized at a HSWA facility, then in light of the lack of a promulgated HSWA regulation on what constitutes appropriate remediation trigger levels, Region 4 HSWA Facility Coordinators are free to use the standard remediation trigger levels offered by CERCLA. As in CERCLA, the actual remediation trigger used at a facility is at the discretion of the EPA Facility Coordinator, but the remediation trigger utilized must be within the Agency's protective range.

Region 4 envisions great flexibility in the phase of the HSWA Corrective Action Program in which a full site-specific human health risk assessment may be implemented. One reasonable location in the corrective action process for performance of a human health risk assessment is as an initial phase within the

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[6] The EPA Soil Screening Level Guidance should be consulted for information on what constitutes a site-specific action level. To summarize the guidance, site-specific residential action levels which address direct soil ingestion and groundwater ingestion should not be generated; however, site-specific inhalation and migration to groundwater action levels can be developed.

[7] Note that the Region 4 HSWA Program has taken the position in the past that a no further action determination (i.e., a final decision on the disposition of a SWMU/AOC without attached conditions such as deed notifications) can only be satisfied when future use is assumed to be residential (see the Region 4 position paper entitled "Media Cleanup Standards and Conditional Remedies" - 1/26/96).

CMS Work Plan (see attached Figure 1; Appendix C of the Region 4 1995 Model HSWA Permit). In this scenario, the CMS Work Plan is triggered by exceedance of one or more standardized or site-specific action levels. With this procedural model, the CMS Work Plan will include an approvable plan/outline which will be followed in performance of the full site-specific risk assessment. The actual evaluation of potential remedial alternatives will be presented after the full site-specific risk assessment is completed and, if remediation triggers are exceeded, RGOs are established.

Some facilities and/or EPA Facility Coordinators may wish to enter into discussions of human risk and remedial measures during the RFI process and before the CMS is imposed. Region 4 sees no hinderance to including EPA approved human health risk assessments as part of the final RFI Report or as a separate document submitted after finalization of the RFI Report but before imposition of the CMS Work Plan (see attached Figure 2). With this procedural model, an approved risk assessment will establish whether or not unacceptable risk exists at the facility (i.e., whether or not the remediation trigger is exceeded). If unacceptable risk exists at the facility, then a CMS would be required (see footnote 7).

Use of full site-specific human health risk assessments is largely untested in Region 4's HSWA Corrective Action Program. However, the CERCLA Program routinely performs risk assessments as part of their Remedial Investigation Reports in order to determine whether unacceptable risks are present at a site. Region 4 recognizes that the upfront performance of a site-specific risk assessment within the RFI Report, between the RFI Report and before the CMS Work Plan or as an initial phase to the CMS (i.e., identification of the range of risks based on current and future exposure scenarios) may serve to streamline the HSWA Corrective Action Process by identifying facilities which may not warrant evaluation of remedial alternatives. In addition, utilizing risk assessments will result in a clarification of Remedial Goal Options (RGOs) which will later be used in developing remedial plans for evaluation in the CMS.

## IV. Ecological Risk Assessments in the HSWA Corrective Action Program

Region 4 believes that ecological risk assessments, if deemed necessary by the EPA Facility Coordinator after conference with an ecological risk assessor, are best performed during the RFI. The science of ecological risk assessments has not reached the point where risk assessors can make standard risk calculations for common risk scenarios, as is done with human risk assessments. Therefore, great professional judgement must be used in determining whether adverse ecological effects are occurring or will occur in the future. For example, unlike common release characterization data which can be easily incorporated into human health risk assessments (e.g., groundwater concentrations, soil concentrations), different types of field data are necessary for an ecological risk assessment to provide risk characterization (e.g., the species to be considered indicative of a healthy habitat must be selected and sampled, the exposure pathway of the target organism (direct adsorption or ingestion) must be selected and hypotheses tested, the methods to evaluate the sampled data must be selected, etc.).

EPA has developed an eight step process for use in designing and conducting ecological risk assessments at CERCLA sites (see Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments; September 26, 1994 (draft)). This document along with the Ecological Risk Bulletins generated by Region 4's OTS should be reviewed for the Agency's latest thoughts on how to plan and conduct studies to estimate the ecological risk from chemicals of concern.

In summary, because so much unique characterization data is necessary for an ecological risk assessment, environmental evaluations, if necessary, are better serviced under the RFI phase of HSWA Corrective Action. For more information on ecological risk assessments within the HSWA Program, please refer to the 1996 ANPRM for corrective action of releases from SWMUs.

## V. Are Risk Assessments Always Necessary in the HSWA Program?

In order to determine that unacceptable risks are present at a facility and to determine acceptable remediation goals, some form of risk analysis is required. This risk analysis may take the form of standard or site-specific risk analysis (i.e., standardized action levels or site-specific action levels - see footnotes 5 and 6) or, if deemed necessary by the facility or

EPA, through a full site-specific quantitative/qualitative risk analysis (i.e., a full site-specific risk assessment).

Region 4 expects there to be cases where the proposed remedial alternative limits or completely eliminates exposure(s) without the need to establish specific numerical remedial goals (i.e., cleanup levels). For example, assuming there are no leachability concerns, if contaminated soil presents unacceptable risks through direct contact and/or air pathway exposure scenarios, then there may be several options. It may be adequate to cap the area and place restrictions on future activities in the area. It may also be feasible to excavate some small areas of highly contaminated soil for cost-effective off-site disposal while covering the remaining soil with clean fill. The type of risk evaluation suggested above may be termed "qualitative risk assessments" while more arithmetic risk assessments may be termed "quantitative risk assessments."

There may also be situations where protective management of contamination can be accomplished without the preparation of a full site-specific risk assessment. In other words, a full site-specific risk assessment may not have to be performed if the facility and EPA agree on a remedial alternative to satisfy risk-developed levels based on standard risk assumptions or promulgated health-based standards. For example, if the proposed remedy for contaminated soil is to remove all contaminated soil to background or conservative residential health-based levels (i.e., action levels), then there is no need for a full site-specific risk assessment.[8] Likewise, if promulgated standards (e.g., maximum contaminant levels (MCLs), surface water quality criteria, etc.) are used as the remedial goals for groundwater,

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[8] Use of action levels as remedial goals (i.e., a cleanup standards) is valid only if certain conditions are met: 1. A single medium is contaminated, 2. A single constituent contributes nearly all of the health risks, 3. Volatilization or leaching of that constituent from soil is expected not to be significant, 4. The exposure scenarios used in calculating the action level are appropriate for the facility, 5. The fixed risk levels used in calculating the action level are appropriate for the facility, 6. Risk to ecological receptors is expected not to be significant.

then no formal risk assessment is necessary (see attached Figure 3).

Because active remediation may not always be necessary to manage unacceptable risks at a HSWA facility, Region 4 expects that conditional remedies will be utilized at many HSWA facilities (see the Region 4 position paper entitled "Media Cleanup Standards and Conditional Remedies"). EPA may select a conditional remedy that protects human health and the environment under plausible exposures conditions during the term of the permit if the following criteria are met:

1. The remedy protects human health and the environment based on current exposures,

2. The remedy achieves conservative media cleanup standards or levels (e.g., MCLs) beyond the facility boundary,

3. The remedy prevents further significant degradation of the environmental media through treatment and/or engineering methods (stabilization),

4. As needed, the remedy includes institutional or other controls to prevent significant exposures (including deed restrictions),

5. The remedy includes continued monitoring to determine whether further significant degradation occurs,

6. The remedy includes financial assurances for the conditional remedy, and

7. The remedy complies with standards for management of wastes.

## VI. Conclusion

Once the RFI process has adequately defined the nature and extent of contamination and found that one or more action levels have been exceeded, then a full site-specific human health risk assessment may be proposed by the facility or required by EPA. Where this assessment occurs in the HSWA Corrective Action Process is one of convenience for the parties involved.

Unlike the CERCLA Program which requires the generation of a full site-specific human health risk assessment at every site, risk assessments do not have to be performed at every HSWA facility. However, if a full site-specific risk assessment is deemed necessary at a HSWA facility, then the methodology, equations, standard intake assumptions, land use assumptions/guidance, etc. historically attributed to CERCLA risk assessments are appropriate for risk assessments performed for the HSWA Corrective Action Program.

Ecological risk assessments require potentially unique data needs and specialized expertise which many EPA Facility Coordinators do not have. Therefore, if, after consultation with an ecological risk assessor, an ecological study is deemed necessary at a HSWA facility, then it is advisable for the ecological study to be initiated as early as possible within the RFI process. As with CERCLA human health risk assessment guidance, CERCLA ecological risk assessment guidance is also appropriate for ecological risk studies performed for the HSWA Corrective Action Program.

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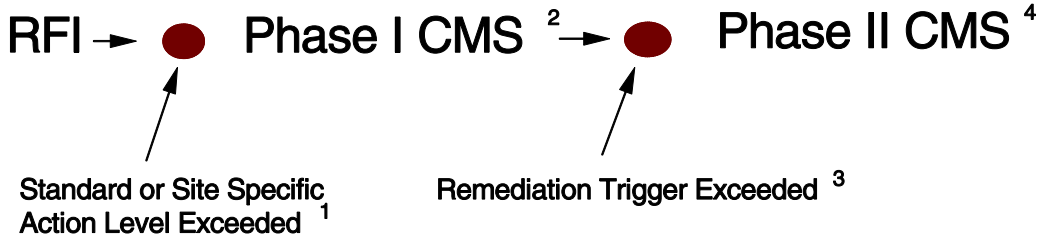
DISCLAIMER

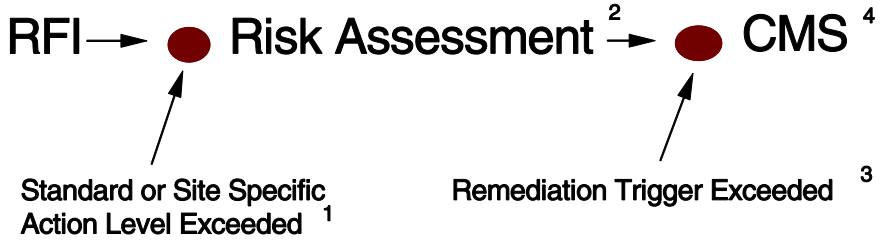
This memo is intended to be a regional interpretation on the use of risk assessments within the HSWA Corrective Action Program. Nothing in this memo is intended to change or supersede future corrective action regulatory requirements. The 1990 Proposed Subpart S rule is currently undergoing renewed review. If any provisions of the revisited Subpart S rule are in conflict with this guidance, then the final regulations will take precedence. The policies and procedures established in this document are intended as guidance for employees of EPA. The policies and procedures are not intended and cannot be relied upon to create any rights, substantive or procedural, enforceable by any party in litigation with the United States. EPA reserves the right to act at variance with these policies and procedures and to change them at any time without public notice.

# FIGURE 1: Procedure to Trigger a CMS with the Risk Assessment as Phase I of the CMS




1. Action Levels are based on residential exposure and have a risk level of $10^{-6}$, a hazard quotient of 1 or exceed chemical specific standards (e.g., MCLs) .
2. A Risk Assessment is performed for Chemicals of Potential Concern (COPC). COPC have a risk level of $10^{-6}$; a hazard quotient of 0.1 or exceed chemical specific standards. Identify Chemicals of Concern and Remedial Goal Options as needed.
3. In general, remediation triggers have a cumulative risk level > $10^{-4}$, a hazard index > 1 or exceed chemical specific standards.
4. Evaluate remedial alternatives using risk levels $10^{-6}$, $10^{-5}$, $10^{-4}$, hazard quotients 0.1, 1 and 3, and chemical specific standards as Remedial Goal Options.

# FIGURE 2: Procedure to Trigger a CMS with the Risk Assessment between RFI and CMS



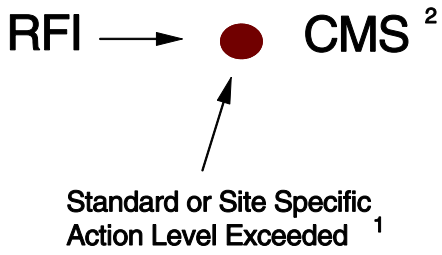

1. Action levels are based on residential exposure and have a risk level of $10^{-6}$, a hazard quotient of 1 or exceed chemical specific standards (e.g., MCLs).

2. A Risk Assessment is performed on Chemicals of Potential Concern (COPC). COPCs have a risk level of $10^{-6}$, a hazard quotient of 0.1 or exceed chemical specific standards. Identify Chemicals of Concern (COC) and Remedial Goal Options (RGO) as needed.

3. In general, remediation triggers have a cumulative risk level > $10^{-4}$ or a hazard index > 1 or exceed chemical specific standards.

4. Evaluate remedial alternatives using risk levels $10^{-6}$, $10^{-5}$ and $10^{-4}$, hazard quotients 0.1, 1 and 3, and chemical specific standards as Remedial Goal Options.

# FIGURE 3: Procedure to Trigger a CMS without use of a Risk Assessment




1 Action levels are based on residential exposure and have a risk level of $10^{-6}$, a hazard quotient of 1 or exceed chemical specific standards (e.g., MCLs).

2. Evaluate remedial alternatives using action levels or chemical specific standards as Remedial Goal Options.

Attachment 1

Office of Technical Services
Supplemental Guidance to RAGS
Region 4 Bulletins - Human Health Risk Assessment
November 1995

See the Office of Technical Services for a hard copy of this document.